

REMARKS

Applicant amended claims 26, 28, 29, 35, 37, 40, 44, and 48, and canceled claims 30-32, 34, 41, 46, and 47. Claims 26, 28, 29, 35-40, 42-45, and 48-52 are presented for examination. The claims as amended require a balloon having a first co-extruded layer comprising a liquid crystal polymer (LCP) and a second co-extruded layer comprising a second polymer.

Claims 26, 28-32, and 34-52 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification. In particular, the rejection states that, prior to this Reply, the claims would cover a single layer balloon having an LCP. Applicant has amended the claims to require a balloon comprising two co-extruded layers, which the Examiner has acknowledged is described in Applicant's specification ("Applicant's disclosure clearly supports a multi-layer balloon (See page 2; Figures 4-6 of the drawings)." Office Action, page 2).

The remaining issue is then whether Applicant's specification limits the LCP-containing layer to a tensile, outer layer, as asserted in the rejection. The rejection reasons that since LCP is disclosed as a material included in the tensile layer, and the tensile layer is described as forming an outer layer only, then LCP can only be included in the outer layer. This reasoning, however, is inconsistent with Applicant's disclosure, which explicitly discloses that a material can be used either in the tensile layer or in the inner layer.

The specification expressly illustrates the use of tensile material as an inner bonding layer. Polyvinyl chloride (PVC) is among a list of examples, including LCP, that can be used in the tensile layer. (See, e.g., page 3, lines 14-36, of the specification.) The specification describes a balloon having PVC as an inner layer and PET as an outer layer. (See, e.g., page 7, line 20, to page 9, line 15, of the specification.) The balloon's inner layer of PVC can be bonded to a catheter body:

While the PVC layer 48 adds little to the burst strength of the composite, it does facilitate the attachment of the balloon to the exterior of the tubular catheter body. (See, page 9, lines 13-15, of the specification.)

*App appears to
be considering LCP
and PVC as equivalent
and not competing or
evident*

(The fact that PVC, as used in a tensile layer, is described in combination with ABS does not negate the exemplary disclosure of the same polymer in the tensile or bonding layer.) Thus, the reasoning in the rejection that a tensile layer material can only be used in the outer layer is inconsistent with Applicant's disclosure.

The specification goes further by expressly describing the concept of a composite balloon made of multiple layers in various combinations to provide user selected combination of properties. For example, the Field of the Invention, Summary and Abstract of the specification convey:

I. Field of the Invention

This invention relates generally to balloon catheters, and more particularly to a method for fabricating a multiplayer balloon composite exhibiting enhanced characteristics attributable to the properties of the individual layers. (p. 1, l. 1-7)

* * * *

The above-listed desirable characteristics are achieved in accordance with the present invention by forming a multi-layer balloon where the individual layers afford a desirable property to the composite. (p. 2, l. 20-23)

* * * *

ABSTRACT

A method of producing laminated inflatable, substantially inextensible expander members having composite properties enhancing their use on intravascular catheters, such as angioplasty catheters is described. Diverse polymeric compounds of differing properties are coextruded to create a multiplayer parison. The parison is subsequently drawn and expanded in a blow molding operation to yield an expander member exhibiting enhanced properties including lubricity, burst-strength, limited radial expansion, bondability, and rupture characteristics. (p. 16)

The specification is also clear the disclosed materials can be used in various combinations (emphasis ours):

It will be appreciated that the particular combination chosen would depend on the particular application and particular catheter involved, and that an array of multi-layer expanders of different composition combinations particularly applicable to different situations can be produced. In addition, specific properties required for addressing a specific stenosis could be utilized to produce a tailor-made expander. (p. 3, l. 14-p. 4, l. 21))

Indeed, in discussing the method of co-extrusion, the specification indicates expressly that an outer tensile layer/inner bonding layer is only an example (emphasis ours):

More particularly with respect to the process, a tubular parison is first generated in a co-extrusion process whereby different polymeric materials are coaxially layered. Subsequently, the parison is inserted in a blow molding fixture, allowing the tube to be longitudinally drawn and radially expanded until the composite film is oriented, the maximum O.D. of the expander member is defined and a desired film thickness is achieved. For example, in forming the parison, PET of a predetermined viscosity may be coextruded with polyethylene where, forming the parison, the polyethylene lines the lumen thereof. When the expander member is formed from the parison in the blow molding operation, the PET layer affords the desired burst strength and limited radial expansion characteristic while the polyethylene layer enhances the ability to bond the resulting balloon to the catheter body. (p. 4, l. 22-35)

As a result, the specification does not limit the use of LCP to the outer tensile layer as the rejection reasons. Instead, the specification broadly conveys the idea of co-extruded balloons using, for example, the polymers listed, such as LCP, in various combinations. It is submitted that a person of ordinary skilled would clearly recognize that Applicant had possession of a multilayer balloon having LCP in the outer layer or in the inner layer.

The drawings were objected to as not showing a medical balloon having a single layer of LCP. As amended, the claims recite at least two co-extruded, which renders the objection moot.

Applicant : Robert N. Hamlin
Serial No. : 09/557,473
Filed : April 24, 2000
Page : 8 of 8

Attorney's Docket No.: 10527-003007 / PC7558F-US

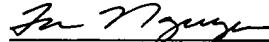
Claims 26, 28-32, and 34-52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,270,086, and over claims 1-25 of U.S. Patent No. 6,132,824. Applicant acknowledges the rejection and intends to file the appropriate terminal disclaimers upon an indication that the claims are otherwise allowable.

Applicant acknowledges the Examiner's indication of allowable subject matter, but in light of the above remarks, Applicant believes that Applicant is entitled to a broader scope of protection.

Enclosed is a Petition for Extension of Time with the required fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: August 8, 2003



Tu N. Nguyen
Reg. No. 42,934

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906